

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 23, 2008 has been entered.

As a result, claims 1-5 and 7-9 and 26 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. Claims 1, 3-5, 7-9 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed April 11, 2008. Applicants traverse in the paper filed May 23, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the present application directs to a process rather than the nucleotide sequence that are used for practicing the claimed process and that a particular nucleic acid is not essential to the claimed method (response, the paragraph bridging pages 5-6).

The office contends that the nucleotide sequences used in the process still need to meet the written description requirement. As discussed in previous actions, only very limited number of genes encoding delta-5- and delta-8-desaturases are disclosed in the prior art and they are not considered be representative of the genus. Further, delta-9-elongase is not well known in the art at the time of the instant invention. Therefore, it is concluded that Applicants are not in possession of a method of using any delta-5-, delta-8-desaturases and delta-9-elongases.

Applicants further argue that possession of an invention can be shown in variety of ways including description of an actual reduction to practice (response, page 6, 3<sup>rd</sup> paragraph).

The Office contends that the reduction to practice may provide support for specific delta-9-elongase, delta-5- and delta-8-desaturase, the reduction to practice fails to show possession for the invention in full scope.

Applicants further argue that since other delta-9-elongase, delta-5- and delta-8-desaturase would be expected to perform the same enzymatic conversions in the context of the claimed process, disclosure of more species is not necessary to show possession of the entire genus (response, page 6, 4<sup>th</sup> paragraph).

The Office contends that the instant invention requires not the enzyme but the nucleotide sequences encoding the enzymes. Therefore, simply knowing the other members would perform the same enzymatic conversions is not enough to show possession of the genus which encompass any nucleotide sequences encoding any delta-9-elongase, delta-5- and delta-8-desaturase from any organism.

5. Claims 1-5, 7-9 and 26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for accumulate C20 polyunsaturated fatty acids in transgenic plant expressing nucleotide sequences encoding SEQ ID NO: 2,4 and 6, does not reasonably provide enablement for any transgenic plant expressing any delta-9-elongase, any delta-5- and delta-8-desaturase to produce any compound shown in formula I of claim 1 with a content of at least 1% by weight. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for the reasons of record stated in the Office

action mailed April 11, 2008. Applicants traverse in the paper filed May 23, 2008.

Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the claimed subject matter relates to a process and the individual genes encoding delta-9-elongase, elta-5- and delta-8-desaturase are not being claimed (response, page 7, 5<sup>th</sup> paragraph). Applicants further argue that it is merely routine experimentation to identify other delta-9-elongase by using instantly-disclosed sequence as a probe (response, the paragraph bridging pages 7-8).

The Office contends that the genes used in the claimed process are not well known especially for delta-9-elongase. Further, to identify and isolate those un-exemplified genes is undue without further guidance. Therefore, in contrast to Applicants' conclusion that to screening and testing delta-9-elongase, any delta-5- and delta-8-desaturase activity in plant is routine and is not undue experimentation, the Office maintains that undue experimentation is required for a person skilled in the art to clone un-exemplified genes encoding delta-9-elongase, any delta-5- and delta-8-desaturase by using PCR or hybridization, to verify its activity, to make the plant expression cassettes expressing all three genes, to transform plants therewith, and to confirm that the transgenic plants have the claimed content for all the compounds described in claim 1. Still further, it is not known whether the nucleotide sequences encoding delta-9-elongases from various plants. Therefore the instant -disclosed sequence may be used as probe to identify other closely related genes from closely related plant species of Arabidopsis, without further guidance undue experimentation

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would have been required to use instant -disclosed sequence as probes to identify other gene encompassed by the claims from not closely related plants.

Still further, the working example in the specification only shows the data for the content of C16, C18 and C20 polyunsaturated fatty acids such as the ones listed in table 1, it does not provide any evidence that other compounds in the formula I of claim 1 are produced by the instant method. There is no evidence that the transgenically expressed enzymes would produce such unmanageable number of compounds as depicted in claim 1.

### ***Summary***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Li Zheng/  
Examiner, Art Unit 1638